APPENDIX OF CLAIMS

1. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;

(b) a subcoating layer comprising an alkaline agent; and

(c) an enteric coating material layered over said subcoating layer; wherein said substrate is characterized in that said substrate does not include an alkaline agent.

2. (Withdrawn) The composition of claim 1, wherein lansoprazole comprises lansoprazole base.

3. (Withdrawn) The composition of claim 1, wherein said substrate features:

(i) a neutral core; and

(ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;

such that the composition is in a form of a pellet.

4. (Withdrawn) The composition of claim 3, wherein said neutral core comprises a non pareil.

5. (Withdrawn) The composition of claim 4, wherein said non-pareil has a range in a size of from about 300 to about 1000 microns.

6. (Withdrawn) The composition of claim 3, wherein said active coating includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC), or a mixture thereof.

7. (Canceled)

8. (Withdrawn) The composition of claim 3, wherein said active coating comprises at least one surfactant selected from the group consisting of of Tween 80 or sodium lauryl sulfate.

9. (Canceled)

10. (Withdrawn) The composition of claim 3, wherein said active coating further comprises at least one filler.

11. (Withdrawn) The composition of claim 10, wherein said at least one filler comprises a suitable grade of lactose.

12. (Withdrawn) The composition of claim 3, wherein said active coating further comprises an aqueous solvent.

13. (Withdrawn) The composition of claim 1, wherein said alkaline agent in said subcoating layer comprises an organic basic salt.

14. (Withdrawn) The composition of claim 13, wherein said organic basic salt includes at least one of sodium stearate.

15. (Withdrawn) The composition of claim 1, wherein said alkaline agent in said subcoating layer comprises an inorganic basic salt.

16. (Withdrawn) The composition of claim 1, wherein said subcoating layer includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and hydroxypropyl cellulose (HPC), or a mixture thereof.

17. (Canceled)

18. (Withdrawn) The composition of claim 1, wherein said subcoating layer comprises at least one surfactant selected from the group consisting of Tween 80 or sodium lauryl sulfate.

19. (Canceled)

20. (Withdrawn) The composition of claim 1, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate,

polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

21. (Withdrawn) The composition of claim 1, wherein said enteric coating material further comprises a plasticizer selected from the group consisting of a citric acid ester and a phthalic acid ester.

22. (Canceled)

23. (Withdrawn) The composition of claim 1, wherein said substrate is an active core for containing lansoprazole.

24. (Withdrawn) The composition of claim 23, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.

25. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;

(b) a subcoating layer for coating said substrate, said subcoating layer consisting essentially of an alkaline agent, a cellulosic polymer, a filler, a surfactant and a solvent; and

(c) an enteric coating material layered over said subcoating layer.

26. (Previously presented) A method for administering a therapeutically effective amount of lansoprazole as sole pharmaceutically active ingredient to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof, wherein said substrate is characterized in that said substrate does not include an alkaline agent,

(b) a subcoating layer for coating said substrate, said subcoating layer consisting essentially sodium stearate, a cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and hydroxypropyl cellulose (HPC), or a mixture thereof, a filler, a

surfactant selected from the group consisting of polysorbate 80 and sodium lauryl sulfate, and a solvent; and

(c) an enteric coating material layered over said subcoating layer.

27. (Previously presented) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof as sole pharmaceutically active ingredient, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer.

28. (Original) The method of claim 27, wherein lansoprazole comprises lansoprazole base.

29. (Previously presented) The method of claim 27, wherein said substrate features:

(i) a neutral core; and

(ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;

such that the composition is in a form of a pellet.

30. (Original) The method of claim 29, wherein said neutral core comprises a non pareil.

31. (Original) The method of claim 30, wherein said non-pareil has a range in a size of from about 300 to about 1000 microns.

32. (Previously presented) The method of claim 29, wherein said active coating includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC) and hydroxypropyl cellulose (HPC), or a mixture thereof.

33. (Canceled)

34. (Previously presented) The method of claim 29, wherein said active coating comprises at least one surfactant selected from the group consisting of polysorbate 80 and sodium laurel sulfate.

35. (Canceled)

36. (Previously presented) The method of claim 29, wherein said active coating further comprises at least one filler.

37. (Previously presented) The method of claim 36, wherein said at least one filler comprises lactose monohydrate.

38. (Previously presented) The method of claim 29, wherein said active coating further comprises an aqueous solvent.

39. (Previously presented) The method of claim 27, wherein said alkaline agent in said subcoating layer comprises an organic basic salt.

40. (Previously presented) The method of claim 39, wherein said organic basic salt comprises sodium stearate.

41. (Previously presented) The method of claim 27, wherein said alkaline agent in said subcoating layer comprises an inorganic basic salt.

42. (Previously presented) The method of claim 27, wherein said subcoating layer includes at least one cellulosic polymer selected from the group consisting of hydroxypropyl methylcellulose (HPMC), ethylcellulose and hydroxypropyl cellulose (HPC), or a mixture thereof.

43. (Canceled)

44. (Previously presented) The method of claim 27, wherein said subcoating layer comprises at least one surfactant selected from the group

consisting of polysorbate 80 and sodium lauryl sulfate.

45. (Canceled)

46. (Previously presented) The method of claim 27, wherein said enteric coating material includes at least one enteric material selected from the group consisting of hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate, cellulose acetate phthalate, cellulose acetate trimellitate, polymethacrylic acid methyl methacrylate and polymethacrylic acid ethyl methacrylate.

47. (Previously presented) The method of claim 27, wherein said enteric coating material further comprises a plasticizer selected from the group consisting of a citric acid ester and a phthalic acid ester.

48. (Canceled)

49. (Original) The method of claim 27, wherein said substrate is an active core for containing lansoprazole.

50. (Original) The method of claim 49, wherein said active core is selected from the group consisting of a pellet, a bead and a tablet.

51. (Withdrawn) A stable composition for lansoprazole, the composition comprising:

(a) a neutral core; and

(b) an active coating containing lansoprazole base, said active coating being layered over said neutral core to form a coated core;

(c) a subcoating layer for coating said coated core, said subcoating layer comprising an alkaline agent; and

(d) an enteric coating material layered over said subcoating layer; wherein said active coating is characterized in that said active coating does not include an alkaline agent and such that the composition is in a form of a pellet.

52. (Withdrawn) The composition of claim 2, wherein said neutral core has a size in a range of from about 80 to about 1000 microns.

53. (Withdrawn) A stable composition for Lansoprazole, the composition comprising:

(a) a substrate, said substrate comprising lansoprazole or a pharmaceutically suitable salt thereof;

(b) a subcoating layer comprising an alkaline agent;

(c) an enteric coating material layered over said subcoating layer to form enteric coated pellets;

wherein said enteric coated pellets are compressed into a tablet dosage form.

54. (Withdrawn) The composition of claim 53, wherein said substrate features:

i) a neutral core; and

ii) an active coating containing lansoprazole, said active coating being layered over said neutral core;

such that the composition is in a form of a pellet.

55. (Withdrawn) The composition of claim 54, wherein said neutral core has a size in a range of from about 80 to about 500 microns.

56. (Withdrawn) The composition of claim 55, wherein said size is in a range of from about 200 to about 300 microns.

57. (Withdrawn) The composition of claim 53, wherein said enteric coating does not include a plasticizer.

58. (Previously presented) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising an active core containing lansoprazole or a pharmaceutically suitable salt thereof as sole pharmaceutically active ingredient and a surfactant, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer.

59. (Previously presented) A method for administering a therapeutically effective amount of lansoprazole to a subject comprising:

administering orally to the subject a stable composition for lansoprazole comprising:

(a) a substrate, said substrate comprising

i) a neutral core; and

ii) an active coating containing lansoprazole or a pharmaceutically suitable salt thereof as sole pharmaceutically active ingredient and a surfactant, said active coating being layered over said neutral core, wherein said substrate is characterized in that said substrate does not include an alkaline agent;

(b) a subcoating layer for coating said substrate, said subcoating layer comprising an alkaline agent comprising sodium stearate; and

(c) an enteric coating material layered over said subcoating layer.